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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/603,891	06/24/2003	Kenneth F. Buechler	071949-6804	4895

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EXAMINER	
JUNG, UNSU	

ART UNIT	PAPER NUMBER
1641	

DATE MAILED: 06/21/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/603,891	BUECHLER ET AL.	
	Examiner	Art Unit	
	Unsu Jung	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 April 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-36* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-36* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1-36 are pending.

Election/Restrictions

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-17 drawn to a method of analyzing a subject sample for a plurality of subject-derived markers selected to distinguish amongst a plurality of cardiovascular disorders, classified in class 435, subclass 13, for example.

II. Claim 18, drawn to a test device for performing a method of analyzing a subject sample for a plurality of subject-derived markers selected to distinguish amongst a plurality of cardiovascular disorders, classified in class 422, subclass 68.1, for example.

III. Claims 19-34, drawn to a method of analyzing a subject sample for a plurality of subject-derived markers selected to distinguish amongst a plurality of cerebrovascular disorders, classified in class 435, subclass 7.1, for example.

IV. Claim 35, drawn to a test device for performing a method of analyzing a subject sample for a plurality of subject-derived markers selected to distinguish amongst a plurality of cerebrovascular disorders, classified in class 435, subclass 287.2, for example.

V. Claim 35, drawn to a test device for performing a method of analyzing a subject sample for a plurality of subject-derived markers selected to identify subjects suffering from myocardial infarction, classified in class 436, subclass 518, for example.

3. The inventions are distinct, each from the other because of the following reasons:

4. Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the product as claimed can be used in a materially different process. For example, the product of Group II can be used to separate/isolate biological analyte of interest in a sample.

5. Inventions I, III, and V are independent and patentably distinct. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the method of Group I includes a step of characterizing a subject's risk of having developed or developing cardiovascular disorders, which is not required by the methods of Groups III and V. The method of Group III includes a step of assaying for the presence or amount of one or more subject-derived markers related to

neural tissue injury, which is not required by the methods of Groups I and V. The method of Group V includes a step of characterizing a subject's risk of having suffered a myocardial infraction, which is not required by the methods of Group I and III. Therefore, the methods of Groups I and III have different modes of operation.

6. Inventions I and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the product as claimed can be used in a materially different process. For example, the product of Group IV can be used to separate/isolate biological analyte of interest in a sample.

7. Inventions II and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the product as claimed can be used in a materially different process. For example, the product of Group II can be used to separate/isolate biological analyte of interest in a sample.

8. Inventions II and IV are independent and patentably distinct. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the device of Group II includes a test surface comprising an antibody immobilized to bind to plurality of subject-derived markers related to myocardial injury, which is not required by the device of Group IV. The device of Group IV includes a test surface comprising an antibody immobilized to bind to plurality of subject-derived markers related to neural tissue injury, which is not required by the device of Group II.

9. Inventions II and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the product as claimed can be used in a materially different process. For example, the product of Group II can be used to separate/isolate biological analyte of interest in a sample.

10. Inventions III and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different

process of using that product. See MPEP § 806.05(h). In the instant case the product as claimed can be used in a materially different process. For example, the product of Group IV can be used to separate/isolate biological analyte of interest in a sample.

11. Inventions IV and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the product as claimed can be used in a materially different process. For example, the product of Group IV can be used to separate/isolate biological analyte of interest in a sample.

12. Because these inventions are independent or distinct for the reasons given above, have acquired a separate status in the art because of their recognized divergent subject matter, and searches for one group are not required by the others, restriction for examination purposes as indicated is proper.

Election of Species within Group I

13. This application contains claims directed to the following patentably distinct species of the claimed invention I. If, Group I is elected, the applicant is required to elect one species (indicated by letters) from each of the following lists of species. For

the species having subspecies (indicated by lower case roman numerals), applicant is further required to elect one subspecies.

List I: blood pressure regulation markers (claims 3 and 4)

a. B-type natriuretic peptide
b. a marker related to B-type natriuretic peptide
c. C-type natriuretic factor
d. urotensin II
e. arginine vasopressin
f. aldosterone
g. angiotensin I
h. angiotensin II
i. angiotensin III
j. bradykinin
k. calcitonin
l. procalcitonin
m. calcitonin gene related peptide
n. adrenomedullin
o. calcyphosine
p. endothelin-2
q. endothelin-3
r. rennin
s. A-type natriuretic peptide
t. urodilatin

List II: myocardial injury markers (claims 3, 4, 8, and 11)

a. free cardiac troponin I
b. free cardiac troponin T
c. cardiac troponin I in a complex comprising one or both of troponin T and troponin C
d. cardiac troponin T in a complex comprising one or both of troponin I and troponin C
e. free and complexed cardiac troponin I
f. free and complexed cardiac troponin T
g. creatine kinase-MB
h. myoglobin
i. glycogen phosphorylase-BB
j. annexin B
k. P-enolase
l. heart-type fatty acid binding protein

m. S-100ao

List III: additional markers (claims 5-14)

a. inflammation markers (claims 5-8)

i. C-reactive protein
ii. interleukin
iii. interleukin-1 receptor agonist
iv. CD54
v. CD106
vi. monocyte chemotatic protein-1
vii. caspase-3
viii. lipocalin-type prostaglandin D synthase
ix. mast cell tryptase
x. eosinophil cationic protein
xi. KL-6
xii. Haptoglobin
xiii. tumor necrosis factor α
xiv. tumor necrosis factor β
xv. fibronectin
xvi. vascular endothelial growth factor

b. coagulation and hemostasis markers (claims 9-14)

i. plasmin
ii. fibrinogen
iii. D-dimer
iv. β-thromboglobulin,
v. platelet factor 4,
vi. fibrinopeptide A
vii. platelet-derived growth factor
viii. prothrombin fragment 1+2
ix. plasmin-α2-antiplasmin complex
x. thrombin-antithrombin III complex
xi. P-selectin
xii. thrombin
xiii. von Willebrand factor
xiv. tissue factor
xv. thrombus precursor protein

List IV: cardiovascular disorders (claim 16)

a. myocardial infarction
b. congestive heart failure
c. acute coronary syndrome
d. unstable angina
e. pulmonary embolism

The species are independent or distinct because each species of molecules has patentably distinct chemical structure and biological function and each species of cardiovascular disorders has patentably distinct pathology.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1, 2, 15, and 17 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Election of Species within Group III

14. This application contains claims directed to the following patentably distinct species of the claimed invention III. If, Group III is elected, the applicant is required to elect one species (indicated by letters) from each of the following lists of species. For the species having subspecies (indicated by lower case roman numerals), applicant is further required to elect one subspecies.

List I: blood pressure regulation markers (claim 21 and 32)

a. B-type natriuretic peptide
b. a marker related to B-type natriuretic peptide
c. C-type natriuretic factor
d. urotensin II
e. arginine vasopressin
f. aldosterone
g. angiotensin I
h. angiotensin II
i. angiotensin III
j. bradykinin
k. calcitonin
l. procalcitonin
m. calcitonin gene related peptide
n. adrenomedullin
o. calcyphosine
p. endothelin-2
q. endothelin-3
r. rennin
s. A-type natriuretic peptide
t. urodilatin

List II: neural tissue injury markers (claims 21 and 32)

a. precerebellin 1
b. cerebillin 1
c. cerebellin 3
d. chimerin 1
e. chimerin 2
f. calbrain

g. calbindin D
h. brain tubulin
i. brain fatty acid binding protein ("B-FABP")
j. brain derived neurotrophic factor ("BDNF")
k. carbonic anhydrase XI
l. CACNA1A calcium channel gene
m. nerve growth factor β
n. atrophin 1
o. apolipoprotein E4-1
p. protein 4.1B
q. 14-3-3 protein
r. ciliary neurotrophic factor
s. creatine kinase-BB
t. C-tau
u. glial fibrillary acidic protein ("GFAP")
v. neural cell adhesion molecule ("NCAM")
w. neuron specific enolase
x. S-100b
y. prostaglandin D synthase
z. neurokinin A
aa. neurotensin
bb. secretagogin

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List III: additional markers (claims 22-28)

a. inflammation markers (claims 22 and 23)
b. coagulation and hemostasis markers (claims 24 and 25)

c. apoptosis markers (claims 26-28)
    i. spectrin
    ii. cathepsin D
    iii. caspase 3
    iv. s-acetyl glutathione
    v. ubiquitin fusion degradation protein 1 homolog

d. acute-phase markers (claims 29-32)

    i. hepcidin
    ii. HSP-60
    iii. HSP-65
    iv. HSP-70
    v. S-FAS ligand
    vi. asymmetric dimethylarginine

vii. matrix metalloprotein 11
viii. matrix metalloprotein 3
ix. matrix metalloprotein 9
x. defensin HBD 1
xi. defensin HBD 2
xii. serum amyloid A
xiii. oxidized LDL
xiv. insulin like growth factor
xv. transforming growth factor β
xvi. E-selectin
xvii. glutathione-S-transferase
xviii. hypoxia-inducible factor-1α
xix. inducible nitric oxide synthase
xx. intracellular adhesion molecule
xxi. lactate dehydrogenase
xxii. monocyte chemoattractant peptide-1
xxiii. n-acetyl aspartate
xxiv. prostaglandin E2
xxv. receptor activator of nuclear factor ligand
xxvi. TNF receptor superfamily member 1A
xxvii. TNFα
xxviii. vascular cell adhesion molecule
xxix. cystatin C.

List II: cerebrovascular disorders (claim 33)

a. ischemic stroke
b. hemorrhagic stroke
c. transient ischemic attack
d. subarachnoid hemorrhage

The species are independent or distinct because each species of molecules has patentably distinct chemical structure and biological function and each species of cerebrovascular disorders has patentably distinct pathology.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 19, 20, and 34 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Election of Species within Group V

15. This application contains claims directed to the following patentably distinct species of the claimed invention V. If, Group V is elected, the applicant is required to elect one species (indicated by letters) from each of the following lists of species. For the species having subspecies (indicated by lower case roman numerals), applicant is further required to elect one subspecies.

List I: myocardial injury markers (claims 36)

n. free cardiac troponin I
o. free cardiac troponin T
p. cardiac troponin I in a complex comprising one or both of troponin T and troponin C
q. cardiac troponin T in a complex comprising one or both of troponin I and troponin C
r. free and complexed cardiac troponin I
s. free and complexed cardiac troponin T

t. creatine kinase-MB
u. myoglobin
v. glycogen phosphorylase-BB
w. annexin B
x. P-enolase
y. heart-type fatty acid binding protein
z. S-100ao

The species are independent or distinct because each species of molecules has patentably distinct chemical structure and biological function.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, no claim is generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

16. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the

requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

17. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Unsu Jung whose telephone number is 571-272-8506. The examiner can normally be reached on M-F: 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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